Analysis of Under Consent Orders:

P-07-0087;

P-08-0200;

P-08-0643, P-08-0642, P-08-0644, and P-08-0664;

P-08-0748 and P-08-0751;

P-09-0245 and P-09-0246;

P-09-0293 and P-09-0294;

P-10-0058, P-10-0059, and P-10-0060;

P-11-0091, P-11-0092, and P-11-0093;

P-12-0450

Annual Report

August 11, 2017 – August 10, 2018 Analytical Summary

Prepared by:

October 2018

Report P-10-18-02

Table of Contents

Objective

The subject consent orders require the Company to analyze representative samples of the initially isolated formulations of the PMN substances at each manufacturing facility for the analytes specified in Table 3 of the consent orders and report the results at initial commencement of manufacture or import and again if any new manufacturing facility is added or if the process of manufacture of the PMN substance or any intermediate thereof is significantly altered. The Company is also required to annually analyze the initially isolated formulations and report these results to EPA, in a cycle complementary to the

In addition to the annual reporting for the initially isolated formulations of the PMN substance, the Company must annually report for the starting material: (1) the average values and range of values, including outlying data, from the routine analyses for the analytes specified in Table 1 of the consent orders and (2) the results of the annual analysis for the analyte specified in Table 2 of the consent orders. This report covers these annual reporting requirements for the starting material. The initially isolated formulations of the PMN substance results are provided in separate reports for their respective consent orders.

Materials and Methods

A. Samples Analyzed

A total of forty (40) lots of were prepared between August 11, 2017 and August 10, 2018 and designated as Lots 59 through 98. Lots 59 through 98 were manufactured and thermally treated at and then shipped to other facilities for conversion

into the PMN substances. In this reporting period, was analyzed at to ensure successful . As required in the consent orders, the has been analyzed for the analytes shown in Tables 1 and 2 of the consent orders.

B. Analytical Methods

Analytical Method for

Determination of residual

of the is determined by GC-FID at by using normalized area percent. Some lots of also get analyzed by GC/MS at , but these additional analyses are not required by consent order.

determination at is achieved by GC-MS analysis of the The above methods are discussed in detail in Report P-10-17-01 entitled: "Analytical Methods for the Analysis of and Initially Isolated Formulations of the PMN Substances Required Under Consent Orders: P-07-0087; P-08-0200; P-08-0643, P-08-0642, P-08-0644, and P-08-0664; P-08-0748 and P-08-0751; P-09-0245 and P-09-0246; P-09-0293 and P-09-0294; P-10-0058, P-10-0059, and P-10-0060; P-10-0148; P-11-0091, P-11-0092, P-11-0093, and P-12-0450"

Results

Analysis of

A summary of the results, including the range, averages, and outlying data, for analytes specified in Table 1 of the consent orders are presented in Table 1-A (GC-FID; and 1-B (GC/MS;

LOT #	Method	conc (%)	conc (%)	conc (%)	conc (%)	conc (%)	conc (%)
Limit		89% min	6% max	1.4 max	0.1% max	1.4% max	0.1% max
59	GC-FID	97.83	<0.004	0.044	<0.004	0.297	<0.004
60	GC-FID	97.652	0.005	0.047	<0.004	0.329	<0.004
61	GC-FID	97.26	<0.004	0.044	<0.004	0.298	<0.004
62	GC-FID	97.755	<0.004	0.04	<0.004	0.247	<0.004
63	GC-FID	97.84	<0.004	0.054	<0.004	0.169	<0.004
64	GC-FID	97.421	<0.004	0.057	<0.004	0.095	<0.004
65	GC-FID	97.52	<0.004	0.024	<0.004	0.043	<0.004
66	GC-FID	98.046	<0.004	0.039	<0.004	0.059	<0.004
67	GC-FID	98.09	<0.004	0.046	<0.004	0.057	<0.004
68	GC-FID	98.235	<0.004	0.037	<0.004	0.067	<0.004
69	GC-FID	97.71	<0.004	0.064	<0.004	0.13	<0.004
70	GC-FID	97.666	<0.004	0.065	<0.004	0.255	<0.004
71	GC-FID	97.71	<0.004	0.089	<0.004	0.16	<0.004
72	GC-FID	97.504	<0.004	0.064	0.006	0.21	<0.004
73	GC-FID	96.98	<0.004	0.072	0.006	0.344	<0.004
74	GC-FID	97.641	<0.004	<0.004	0.007	0.397	<0.004
75	GC-FID	98.06	<0.004	0.071	<0.004	0.076	<0.004
76	GC-FID	97.991	0.004	<0.004	0.015	0.211	<0.004
77	GC-FID	97.64	<0.004	0.006	0.007	0.33	<0.004
78	GC-FID	97.744	<0.004	0.029	0.007	0.325	0.005
79	GC-FID	97.81	<0.004	0.08	0.008	0.312	0.006
80	GC-FID	97.938	<0.004	0.04	0.006	0.336	0.008
81	GC-FID	98.24	<0.004	0.015	0.005	0.246	0.006
82	GC-FID	97.815	0.004	0.011	0.012	0.269	<0.004
83	GC-FID	97.98	<0.004	0.01	0.009	0.212	<0.004
84	GC-FID	98.29	<0.004	0.02	<0.004	0.199	0.005
85	GC-FID	98.23	<0.004	0.016	0.01	0.165	<0.004
86	GC-FID	98.374	<0.004	0.044	0.005	0.038	0.004
87	GC-FID	98.13	<0.004	0.102	0.004	0.105	0.011
88	GC-FID	98.257	<0.004	0.08	0.007	0.104	0.012
89	GC-FID	98.05	<0.004	0.064	0.007	0.243	0.015
90	GC-FID	98.63	<0.004	0.137	<0.004	<0.004	<0.004
91	GC-FID	97.32	0.008	0.258	<0.004	<0.004	0.006
92	GC-FID	97.841	<0.004	0.172	0.009	0.183	0.014
93	GC-FID	97.61	<0.004	0.153	0.006	0.117	0.016
94	GC-FID	98.12	<0.004	0.074	0.006	0.127	0.013
95	GC-FID	97.92	<0.004	0.193	<0.004	0.119	0.008
96	GC-FID	98.021	<0.004	0.129	0.014	0.091	0.009
97	GC-FID	97.86	<0.004	0.065	0.006	0.235	0.013

98	GC-FID	97.563	<0.004	0.163	0.016	0.137	0.012
Avg		97.86	<0.004	0.07	0.005	0.18	0.005
Range		96.982 - 98.630	<0.004 - 0.008	0.006 - 0.258	<0.004 - 0.0016	0.038 - 0.397	<0.004 - 0.016

Table 1-A

LOT #	Method	*conc (%)*	*conc (%)*	*conc (%)*
Limit		6% max	0.1% max	0.1% max
71	GC/MS	<0.0002	<0.0002	<0.0002
73	GC/MS	<0.0002	<0.0002	<0.0002
74	GC/MS	<0.0002	<0.0002	<0.0002
75	GC/MS	<0.0002	<0.0002	<0.0002
76	GC/MS	<0.0002	<0.0002	<0.0002
77	GC/MS	<0.0002	<0.0002	<0.0002
78	GC/MS	<0.0002	<0.0002	<0.0002
79	GC/MS	<0.0002	<0.0002	<0.0002
80	GC/MS	<0.0002	<0.0002	<0.0002
81	GC/MS	<0.0002	<0.0002	<0.0002
82	GC/MS	<0.0002	<0.0002	<0.0002
83	GC/MS	<0.0002	<0.0002	<0.0002
84	GC/MS	<0.0002	<0.0002	<0.0002
85	GC/MS	<0.0002	<0.0002	<0.0002
86	GC/MS	<0.0002	<0.0002	<0.0002
87	GC/MS	<0.0002	<0.0002	<0.0002
88	GC/MS	<0.0002	<0.0002	<0.0002
89	GC/MS	<0.0002	<0.0002	<0.0002
90	GC/MS	<0.0002	<0.0002	<0.0002
91	GC/MS	<0.0002	<0.0002	<0.0002
92	GC/MS	<0.0002	<0.0002	<0.0002
93	GC/MS	<0.0002	<0.0002	<0.0002
Avg		<0.0002	<0.0002	<0.0002
Range		<0.0002 - <0.0002	<0.0002 - <0.0002	<0.0002 - <0.0002

Table 1-B

The results for the analyte specified in Table 2 of the consent orders are presented in Table 2

LOT #	*conc (PPM)*
Limit	2 ppm max
59	<2
60	<2
61	<2
62	<2
63	<2
64	<2
65	<2
66	<2
67	<2
68	<2
69	<2
70	<2
71	<2
72	<2
73	<2
74	<2
75	<2
76	<2
77	<2
78	<2
79	<2
80	<2
81	<2
82	<2
83	<2
84	<2
85	<2
86	<2
87	<2
88	<2
89	<2
90	<2
91	<2
92	<2
93	<2
94	<2
95	<2

96	<2
97	<2
98	<2
Avg	<2
Range	<2 - <2

Table 2

Conclusion

Per the subject consent orders, the starting material manufactured and used to produce PMN substance between August 11, 2017 and August 10, 2018 was analyzed and reported for: (1) the average values and range of values, including outlying data, from the routine analyses for the analytes specified in Table 1-A and 1-B of the consent orders and (2) the results of the annual analysis for the analyte specified in Table 2 of the consent orders.